Remarks

I. Status of the Claims

Reconsideration of this application is respectfully requested.

Upon entry of the foregoing amendment, claims 1, 7, 30-36 and 40-41 are pending in the application, with claims 1, 7 and 30 being the independent claims.

Claim 41 has been added, and claims 1, 7 and 30 have been amended to (a) add SEQ ID NO:1; (b) add an adjuvant; (c) add the recitation of "a single dose preparation or a multi-dose flask;" and (d) remove recitation of "fragments" of the recited sequences. Support for the claim amendments may be found in the originally-filed claims and in the specification, including on page 29, line 2 to page 30, line 17, and page 63, lines 5. Accordingly, these changes introduce no new matter and their entry is respectfully requested. The amendments are made without prejudice to or disclaimer of the subject matter of un-amended claims and Applicants reserve the right to pursue such subject matter in subsequent applications.

The Examiner has withdrawn claims 35, 36 and 40 as being drawn to nonelected species. Upon the identification of allowable subject matter in generic or linking claims, Applicants respectfully request the rejoinder and consideration of the non-elected species, in accordance with 37 C.F.R. § 1.141.

Based on the above amendments and the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding objections and rejections and that they be withdrawn.

II. Rejection Under 35 U.S.C. § 112, First Paragraph, Written Description

The Examiner has maintained the rejection of claims 1, 7 and 30 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. *See* Office Action at pages 3-4, § 8. The Examiner states that claims 1, 7 and 30 lack sufficient written description support for "fragments" of the recited sequences. Applicants respectfully disagree with the rejection as applied to the presently amended claims.

Claims 1, 7 and 30 have been amended to cancel "fragments" of the recited sequences. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, first paragraph.

III. Rejections Under 35 U.S.C. § 103

The Examiner has maintained the rejection of claims 1 and 31 under 35 U.S.C. § 103 over Furata *et al.* (*Nat. Struct. Biol. 5*:276-279, hereinafter "Furata") in view of Wild *et al.* (WO 94/02505, hereinafter "Wild"). *See* Office Action at pages 4-5, §§ 10-11. The Examiner has also maintained the rejection of claims 1, 7 and 30-34 under 35 U.S.C. § 103 over Furata in view of Wild and further in view of Haddrick *et al.* (*J. Virol. Methods 61*:89-93, hereinafter "Haddrick"). *See* Office Action at page 6, § 12. Applicants respectfully traverse the rejections as applied to the presently amended claims.

Applicants have amended claims 1, 7 and 30 to recite the elements (a) an adjuvant; and (b) a single dose preparation or a multi-dose flask. Adjuvants are well-known in the immunology and pharmaceutical arts, and are described in the present specification, for example, at pages 29-30 and 63. "Single dose" and "multi-dose"

preparations are terms of the pharmaceutical arts that relate to formulations for administration to animals. *See*, e.g., The United States Pharmacopeia, the National Formulary, USP 23, NF 18, page 11, The United States Pharmacopeial Convention, Inc., Rockville, MD (1994) (copy attached as Exhibit 1).

There is no teaching or suggestion in any of the cited references that a compound comprising an HIV gp41/gp120 complex, at least one stabilizing peptide, and a soluble CD4 (a) should be combined with an adjuvant, or (b) should be prepared for administration to an animal. Because the cited references do not disclose all elements of the presently pending claims, the claims are not rendered obvious by the references.

Accordingly, Applicants respectfully request the reconsideration and withdrawal of the rejections under 35 U.S.C. § 103.

Conclusion

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance, or in better condition for appeal. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

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USP 23

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nature, is provided in the reference table *Description and Relative Solubility of USP and NF Articles* in this Pharmacopeia for those who use, prepare, and dispense drugs and/or related articles, solely to indicate properties of an article complying with monograph standards. The properties are not in themselves standards or tests for purity even though they may indirectly assist in the preliminary evaluation of an article.

Solubility—The statements concerning solubilities given in the reference table *Description and Relative Solubility of USP and NF Articles* for Pharmacopeial articles are not standards or tests for purity but are provided primarily as information for those who use, prepare, and dispense drugs and/or related articles. Only where a quantitative solubility test is given, and is designated as such, is it a test for purity.

The approximate solubilities of Pharmacopeial substances are indicated by the descriptive terms in the accompanying table.

Descriptive Term	Parts of Solvent Required for 1 Part of Solute
Very soluble	Less than 1
Freely soluble	From 1 to 10
Soluble	From 10 to 30
Sparingly soluble	From 30 to 100
Slightly soluble	From 100 to 1000
Very slightly soluble	From 1000 to 10,000
Practically insoluble, or Insoluble	10,000 and over

Soluble Pharmacopeial articles, when brought into solution, may show traces of physical impurities, such as minute fragments of filter paper, fibers, and other particulate matter, unless limited or excluded by definite tests or other specifications in the individual monographs.

PRESCRIBING AND DISPENSING

Prescriptions for compendial articles shall be written to state the quantity and/or strength desired in metric units unless otherwise indicated in the individual monograph (see also *Units of Potency* in these *General Notices*). If an amount is prescribed by any other system of measurement, only an amount that is the metric equivalent of the prescribed amount shall be dispensed.

PRESERVATION, PACKAGING, STORAGE, AND LABELING

Containers—The *container* is that which holds the article and is or may be in direct contact with the article. The *immediate container* is that which is in direct contact with the article at all times. The *closure* is a part of the container.

Prior to its being filled, the container should be clean. Special precautions and cleaning procedures may be necessary to ensure that each container is clean and that extraneous matter is not introduced into or onto the article.

The container does not interact physically or chemically with the article placed in it so as to alter the strength, quality, or purity of the article beyond the official requirements.

The Pharmacopeial requirements for the use of specified containers apply also to articles as packaged by the pharmacist or other dispenser, unless otherwise indicated in the individual monograph.

Tamper-resistant Packaging—The container or individual carton of a sterile article intended for ophthalmic or otic use, except where extemporaneously compounded for immediate dispensing on prescription, shall be so sealed that the contents cannot be used without obvious destruction of the seal.

Articles intended for sale without prescription are also required to comply with the tamper-resistant packaging and labeling requirements of the FDA where applicable.

Preferably, the immediate container and/or the outer container or protective packaging utilized by a manufacturer or distributor for all dosage forms that are not specifically exempt is designed so as to show evidence of any tampering with the contents.

Light-resistant Container (see *Light Transmission* under *Containers* ⟨661⟩)—A light-resistant container protects the contents from the effects of light by virtue of the specific properties of the material of which it is composed, including any coating applied to it. Alternatively, a clear and colorless or a translucent container may be made light-resistant by means of an opaque covering, in which case the label of the container bears a statement that the opaque covering is needed until the contents are to be used or administered. Where it is directed to "protect from light" in an individual monograph, preservation in a light-resistant container is intended.

Where an article is required to be packaged in a light-resistant container, and if the container is made light-resistant by means of an opaque covering, a single-use, unit-dose container or mnemonic pack for dispensing may not be removed from the outer opaque covering prior to dispensing.

Well-closed Container—A well-closed container protects the contents from extraneous solids and from loss of the article under the ordinary or customary conditions of handling, shipment, storage, and distribution.

Tight Container—A tight container protects the contents from contamination by extraneous liquids, solids, or vapors, from loss of the article, and from efflorescence, deliquescence, or evaporation under the ordinary or customary conditions of handling, shipment, storage, and distribution, and is capable of tight re-closure. Where a tight container is specified, it may be replaced by a hermetic container for a single dose of an article.

A gas cylinder is a metallic container designed to hold a gas under pressure. As a safety measure, for carbon dioxide, cyclopropane, helium, nitrous oxide,

and oxygen, the Pin-index Safety System of matched fittings is recommended for cylinders of Size E or smaller.

NOTE—Where packaging and storage in a *tight container* or a *well-closed container* is specified in the individual monograph, the container utilized for an article when dispensed on prescription meets the requirements under *Containers—Permeation* ⟨671⟩.

Hermetic Container—A hermetic container is impervious to air or any other gas under the ordinary or customary conditions of handling, shipment, storage, and distribution.

Single-unit Container—A single-unit container is one that is designed to hold a quantity of drug product intended for administration as a single dose or a single finished device intended for use promptly after the container is opened. Preferably, the immediate container and/or the outer container or protective packaging shall be so designed as to show evidence of any tampering with the contents. Each single-unit container shall be labeled to indicate the identity, quantity and/or strength, name of the manufacturer, lot number, and expiration date of the article.

Single-dose Container (see also *Containers for Injections* under *Injections* ⟨1⟩)—A single-dose container is a single-unit container for articles intended for parenteral administration only. A single-dose container is labeled as such. Examples of single-dose containers include pre-filled syringes, cartridges, fusion-sealed containers, and closure-sealed containers when so labeled.

Unit-dose Container—A unit-dose container is a single-unit container for articles intended for administration by other than the parenteral route as a single dose, direct from the container.

Multiple-unit Container—A multiple-unit container is a container that permits withdrawal of successive portions of the contents without changing the strength, quality, or purity of the remaining portion.

Multiple-dose Container (see also *Containers for Injections* under *Injections* ⟨1⟩)—A multiple-dose container is a multiple-unit container for articles intended for parenteral administration only.

Storage Temperature—Specific directions are stated in some monographs with respect to the temperatures at which Pharmacopeial articles shall be stored, when stability data indicate that storage at a lower or a higher temperature produces undesirable results. Such directions apply except where the label on an article states a different storage temperature on the basis of stability studies of that particular formulation. The conditions are defined by the following terms.

Freezer—A place in which the temperature is maintained thermostatically between −20° and −10° (−4° and 14°F).

Cold—Any temperature not exceeding 8° (46°F). A *refrigerator* is a cold place in which the temperature is maintained thermostatically between 2° and 8° (36° and 46°F).

Cool—Any temperature between 8° and 15° (46° and 59°F). An article for which storage in a *cool place* is directed may, alternatively, be stored in a *refrigerator*, unless otherwise specified by the individual monograph.

Room Temperature—The temperature prevailing in a working area.

Controlled Room Temperature—A temperature maintained thermostatically that encompasses the usual and customary working environment of 20° to 25° (68° to 77°F); that results in a mean kinetic temperature calculated to be not more than 25°; and that allows for excursions between 15° and 30° (59° and 86°F) that are experienced in pharmacies, hospitals, and warehouses. Articles may be labeled for storage at "controlled room temperature" or at "up to 25°", or other wording based on the same mean kinetic temperature. The mean kinetic temperature is a calculated value that may be used as an isothermal storage temperature that simulates the nonisothermal effects of storage temperature variations. (See also *Stability* under *Pharmaceutical Dosage Forms* ⟨1151⟩.)

An article for which storage at *Controlled room temperature* is directed may, alternatively, be stored in a *cool place*, unless otherwise specified in the individual monograph or on the label.

Warm—Any temperature between 30° and 40° (86° and 104°F).

Excessive Heat—Any temperature above 40° (104°F).

Protection from Freezing—Where, in addition to the risk of breakage of the container, freezing subjects an article to loss of strength or potency, or to destructive alteration of its characteristics, the container label bears an appropriate instruction to protect the article from freezing.

Storage under Nonspecific Conditions—For articles, regardless of quantity, where no specific storage directions or limitations are provided in the individual monograph, it is to be understood that conditions of storage and distribution include protection from moisture, freezing, and excessive heat.

Labeling—The term "labeling" designates all labels and other written, printed, or graphic matter upon an immediate container of an article or upon, or in, any package or wrapper in which it is enclosed, except any outer shipping container. The term "label" designates that part of the labeling upon the immediate container.

A shipping container, unless such container is also essentially the immediate container or the outside of the consumer package, is exempt from the labeling requirements of this Pharmacopeia.

Articles in this Pharmacopeia are subject to compliance with such labeling requirements as may be promulgated by governmental bodies in addition to the Pharmacopeial requirements set forth for the articles.

Amount of Ingredient per Dosage Unit—The strength of a drug product is expressed on the con-